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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/659,413
Filing Date: September 10, 2003
Appellant(s): KITE ET AL.

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For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 08/23/06 appealing from the Office action mailed 02/24/2006.

(1) Real Party in Interest

A statement identifying the real party of interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The statement of the status of amendments after final rejection contained in the brief is correct. No claims were amended after final rejection.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the issues in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 00/13656	Fahim	03-2000
US 6,500,861	Wilder	12-2002
GB 1 279 148	Kurginski	06-1972

Remington's Pharmaceutical Sciences.

Root et al. Antimicrobial Agents and Chemotherapy. Nov. 1998, pages 1627-1631.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC § 103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 34, 39, 41, 42, 45, and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656) above, in view of Wilder (US 6,500,861, PTO-892).

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight EDTA or its sodium salts such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-

10. It is also taught that the viscosity of the composition can be adjusted by adding sodium chloride. See page lines 15-16. The antimicrobial properties of the compositions were also reported. It is further taught that by increasing the EDTA-Na4 concentration from 2 to 3.0 % by weight provided a substantial increase in bacteria reduction. See page 23, Table 8, prototype 10, wherein the composition comprises 3 % by weight of tetra sodium EDTA, NaCl, water and a pH of 9.5. The antimicrobial compositions comprising tetra-sodium EDTA taught by Fahim are used for topical application such as for cleaning skin. See page 41, claims 35-37.

Fahim does not expressly teach that the composition is packaged in a sterile, pyrogen free form.

Wider teaches antimicrobial compositions for eliminating infections from various surfaces and materials, including the surface of the body. It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

One of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as

conventional with antimicrobial compositions with the expectation of using the composition in catheters.

While the references does not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", as in claim 55, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same tetrasodium EDTA as that recited in the instant invention, the composition should possess claimed properties.

While the references does not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same salts of EDTA as that recited in the instant invention, the composition should possess claimed properties.

In claim 56, the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wider (US 6,500,861 B1), as applied to Claims 32, 34, 39, 41, 42, 45, and 55-60 above, and further in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631, PTO-892).

Fahim, and Wider are as discussed above.

Fahim does not specifically teach the antimicrobial composition in a single-dosage vial.

Root et al. teaches a method for disinfecting a catheter by contacting (flushing) with an antimicrobial composition of aqueous EDTA solution having a concentration of 20 mg/ml. The EDTA used by Root et al. is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative infections. See page 1627, paragraphs 3, and 6. Root further teaches a sterile polystyrene test tubes (vials) containing the antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2 %). See page 1628, lines 18-21.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile condition in a single-dosage vial from the teachings of Root et al.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656, PTO-892), in view of Wilder (US 6,500,861, PTO-892), as applied to 32,

34, 39, 41, 42, 45, and 55-60 above, and further in view Remington's Pharmaceutical Sciences.

Fahim fails to recite the employment of the composition in a prefilled syringe.

Remington's Pharmaceutical Sciences teaches sterile, pyrogen free solutions of sodium chloride as ideal for injection. It also discloses that hypodermic syringes are used for injection of liquids. See page 1837. Remington also warns against injection of solutions containing pyrogens (See page 835, column 2, paragraph 1), and to maintain conventional sterile methodology for injected medicaments.

Possessing this teaching by Remington Pharmaceutical Sciences the skilled artisan would have been motivated to provide a syringe filled with an EDTA solution with the expectation of using such sterile, pyrogen free solution for injection.

Claims 32, 34, 37, 41, 42, 45, 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148, PTO-892 of record), in view of Fahim (WO 00/13656), and Wilder (US 6,500,861 B1).

Kurginski teaches a composition comprising alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 %, a loweralkanol of 1 to 4 carbon atoms in the amount of 1 to 5 parts i.e less than 10 %, (such as methanol, ethanol etc), an alkanolamine in an amount of 0.8 to 6 parts, a mixture of two or more different loweralkyl ether alcohols in an amount of 1 to 5 parts, and the rest is water in an amount to complete said composition, for cleaning soils that accumulate in toilets and sanitary facilities due to bacterial and fungal growth

by applying to the surface said composition. See page 1, lines 12-15; lines 61-64. The PH of the composition is from 7 to 12. See page 2, lines 17-22, lines 48-52, lines 59-60; page 4, claims 1, 4, 5. See EXAMPLE 1, page 4, wherein tetrasodium salt of ethylenediaminetetraacetic acid is used, and the pH is 10.2.

Kurginski does not expressly teach that the composition is packaged in a sterile, pyrogen free form.

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight of a salt of EDTA such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10.

Wilder teaches antimicrobial compositions for eliminating infections from various surfaces and materials including the surface of the body. .It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the compositions comprising sodium salts of EDTA as antimicrobial composition, as Fahim teaches that the compositions comprising tetra-sodium EDTA can be used as antimicrobial compositions.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

Thus from the teachings of Fahim, and Wilder, one of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

While the references does not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60 is the property of the composition, since Kurginski discloses the same sodium salt of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Kurginski discloses the same sodium salt of EDTA as that recited in the instant invention, the composition should possess claimed properties.

(10) Response to Argument

1) 103(a)-Fahim in view of Wilder

Claims 32, 34, 39, 41, 42, 45, and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656) above, in view of Wilder (US 6,500,861).

Appellant argues that "one skilled in the art would not modify the handwash of Fahim with the teachings of Wilder to arrive at the claimed compositions. That is, one skilled in the art, aware of Wilder's alleged teaching of antimicrobial compositions packaged in a sterile, pyrogen free form and designed for treatment of internal body spaces or organs, would not be motivated to modify a handwash composition to make it a sterile, pyrogen free form". See page 4-6 of the Brief.

In response, it is pointed out that Fahim teaches antimicrobial compositions for cleaning skin comprising about 0.025 to about 8.0 % by weight EDTA or its sodium salts such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. Wilder teaches antimicrobial compositions used for eliminating infections from various surfaces, including the surface of the body are packaged in a sterile and pyrogen free form. See abstract, wherein it is disclosed that the compositions therein are useful for eliminating infection on the epidermis of the body; see column 6, lines 53-55 wherein it is taught that the antimicrobial composition therein is sprayed onto skin. It would have been obvious to a person of ordinary skill in the art at the time of invention to pack the antimicrobial composition of Fahim employed for skin care application in a sterile and pyrogen free form. One of ordinary skill in the art would have been motivated to prepare the antimicrobial composition of Fahim in a sterile and pyrogen free form with the expectation of success of employing the composition for eliminating infections from epidermis of the body because 1) Wider teaches antimicrobial compositions for eliminating infection on the epidermis of the body are effective when packaged in a sterile and pyrogen free form, and 2) both Fahim and Wilder teach that antimicrobial compositions therein are useful for eliminating an infection on the epidermis of the body.

Applicant's remarks that "the applications of Wilder are contemplated for contact with skin that is not normally exposed (i.e., broken, cut skin)." See page 6-page 7 of the Brief.

In response, it is pointed out that Wilder teaches the compositions therein to be used for eliminating an infection on the epidermis of the body of the user where infection is encountered. See abstract; column 5, lines 63-64. It is also pointed that Wilder teaches application of the antimicrobial compositions therein to be used to eliminate all superficial microorganisms on the surface of the skin. See column 6, lines 53-56. It is pointed out that, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983).

Appellant argues that "One skilled in the art would understand that Wilder is not suggesting that a composition be placed in a sterile and pyrogen free form for other (non "internal spaces") purposes. Thus, Wilder does not teach or suggest the use of a composition in a "sterile and pyrogen free" form for anything but the treatment of internal spaces." See page 7-8 of the Brief.

In response, it is pointed out that as discussed above, Wilder teaches antimicrobial compositions for eliminating an infection on the epidermis of the body, and

also teaches that the compositions therein are in sterile, pyrogen free form. Note, that the Wilder teaches that the compositions in concentrate form are diluted with pyrogen-free water to form an effective use solution. See abstract. Thus, Wilder teaches that the pyrogen free water provides the compositions therein to be effective for eliminating infection in general including the epidermis of the body of the user.

Applicant's argues that "There is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into contact with the user in a manner where packaging in a sterile, non-pyrogenic form would be beneficial." See page 8 of the Brief.

In response, it is pointed out that that a composition for cleaning skin such as that taught by Wilder wherein the composition is sprayed onto skin for eliminating an infection on the epidermis of the body prior to surgical incision is known to be in sterile, non-pyrogenic form. Thus, it would have been obvious to a person of ordinary skill in the art at the time of invention to package an antimicrobial composition for cleaning skin in a sterile, non-pyrogenic form with the expectation of employing for removing superficial microorganism from skin prior to surgical incision.

Claim 56:

Appellant argues that "There is no suggestion that any composition of Fahim, even if it were packaged in a sterile, non-pyrogenic form, would be biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes as specified in claim 56." See page 10 of the Brief.

In response, it is respectfully pointed out that Fahim is not required to do so. Fahim was used in combination with Wilder. This combination discloses that the

antimicrobial compositions therein in sterile pyrogen free form are employed for eliminating infections from the epidermis of the body. Further, it is pointed out that Fahim discloses antimicrobial compositions comprising tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. The compositions taught by Fahim are used for skin care applications i.e they come in contact with skin, and are thus, biocompatible. Further, it is also pointed out that the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 58 and 59

Appellant argues that "Fahim does not teach or suggest that the EDTA salt, provided as an optional component in the antimicrobial combination composition, provides at least 50 % of a total antimicrobial activity of the composition." See page 11 of the Brief.

In response, contrary to appellants argument, it is pointed out that Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight tetra sodium EDTA. See pages 37-38, claims 15-17. The compositions comprising tetra sodium EDTA salt can comprise other antimicrobial agents such as triclosan, PCMX, glutaraldehyde in variable amounts, wherein tetra sodium EDTA salt can be present in an amount from 0.05 to about 6.0 %. Thus, the compositions taught by Fahim will

broadly encompass instantly claimed limitation wherein the antimicrobial combination composition provides at least 50 % of a total antimicrobial activity of the composition because the ingredients are present in variable amounts.

2) 103(a)-Fahim in view of Wilder and further in view of Root et al.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wider (US 6,500,861 B1), as applied to Claims 32, 34, 39, 41, 42, 45, and 55-60 above, and further in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631, PTO-892).

Appellant argues that "one of ordinary skill in the art would not be motivated by Root et al.'s use of sterile test tubes in experimental protocols to package the antimicrobial handwash composition of Fahim in a sterile, non-pyrogenic form in a single-dosage vial." See page 13 of the Brief.

In response, as discussed above there is clear motivation to package an antimicrobial cleaning solution for eliminating infections on the epidermis of the body in a sterile pyrogen free form as discussed above, see Fahim in view of Wilder. Further, Root teaches antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2 %) in sterile polystyrene test tubes (vials). Thus, Root provides clear motivation to package the sterile, non-pyrogenic compositions of EDTA in a single-dosage vial because both Fahim, and Root teach that antimicrobial compositions comprising EDTA salts therein are useful for eliminating an infection. One of ordinary skill in the art would have been motivated at the time of invention to pack the pyrogen-

free, sterile antimicrobial EDTA-salt compositions in single dosage vial with the expectation of employing the compositions in experimental protocols.

3) 103(a)-Fahim in view of Wilder and further in view of Remington's Pharmaceutical Sciences

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656, PTO-892), in view of Wilder (US 6,500,861, PTO-892), as applied to 32, 34, 39, 41, 42, 45, and 55-60 above, and further in view Remington's Pharmaceutical Sciences.

Appellant argues that "Reliance on Remington's Pharmaceutical Sciences to provide a teaching or motivation to provide handwash composition of Fahim in a sterile, non-pyrogenic form in a prefilled syringe is unfounded." See page 14 of the Brief.

In response, it is pointed out that Remington discloses that hypodermic syringes are routinely used for injection of liquids. Possessing this teaching the skilled artisan would have been motivated to provide a syringe filled with an EDTA composition taught by Fahim, for use recited by Widler, and enjoy a reasonable expectation of success. The skilled artisan would see a pre-filled hypodermic syringe as a vial, bottle useful for multiple uses, absent information to the contrary.

For the same reasons as discussed above, said claims are properly rejected under 35 U.S.C.103(a).

4) 103(a) Kurginski in view of Fahim and in view of Wilder

Claims 32, 34, 37, 41, 42, 45, 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148, PTO-892 of record), in view of Fahim (WO 00/13656), and Wilder (US 6,500,861 B1).

Appellant argues that " There is no indication in Kurginski that the composition of Kurginski, optionally containing tetra-sodium EDTA, has any antimicrobial properties." See page 16 of the Brief.

In response, Kurginski teaches a composition comprising alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 %, a loweralkanol of 1 to 4 carbon atoms in the amount of 1 to 5 parts i.e less than 10 %, (such as methanol, ethanol etc), an alkanolamine in an amount of 0.8 to 6 parts, a mixture of two or more different loweralkyl ether alcohols in an amount of 1 to 5 parts, and the rest is water in an amount to complete said composition, for cleaning soils that accumulate in toilets and sanitary facilities due to bacterial and fungal growth. Thus, contrary to applicant's argument the composition taught by Kurginski possess antibacterial and antifungal activity because Kurginski clearly teaches that the composition therein is used to remove soils that accumulate due to bacterial and fungal growth. See page 2, lines 9-10, wherein it is taught that the compositions therein remove gelatinous microorganism.

Applicant argues that "Even if one skilled in the art would be motivated to employ the toilet cleaning compositions of Kurginski as an antimicrobial handwash, there is no suggestion or motivation, whatsoever, to package the composition of Kurginski in a sterile, non-pyrogenic form." See page 16-page 17 of the Brief.

In response, it is pointed out that applicant is arguing against a single reference, when the rejection is based on combination of references. It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial tetrasodium EDTA compositions taught by Kurginski in a sterile, pyrogen free form because 1) Fahim teaches that the antimicrobial compositions comprising tetra-sodium EDTA are used for cleansing skin i.e to eliminate infections on skin, and 2) Wilder teaches that antimicrobial compositions used to treat infections on epidermis are packaged in a sterile, pyrogen free form. Thus, one of ordinary skill in the art would been motivated to pack the antimicrobial EDTA composition taught by Kurginski in a sterile, non-pyrogenic form with reasonable expectation of using the composition to treat infections on epidermis.

Apellant argues that "There is no suggestion that any composition of Kurginski, even if it were packaged in a sterile, non-pyrogenic form, would be biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes, as specified in claim 56." See page 18 of the Brief.

In response, it is pointed out that applicant is arguing against a single reference, when the rejection was based on a combination of references. Further, the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Appellant argues that " Neither Kurginski nor Fahim nor Widler makes any suggestion to combine the teaching as proposed by the Examiner, and there is no motivation to make any such combination. Furthermore, even if the combination were made, the combination does not result in the appellants' claimed compositions, in which the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition." See page 19 of the Brief.

In response, it is pointed out that the composition disclosed by Kurginski comprises alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 %, a loweralkanol of 1 to 4 carbon atoms in the amount of 1 to 5 parts i.e less than 10 %, (such as methanol, ethanol etc), an alkanolamine in an amount of 0.8 to 6 parts, a mixture of two or more different loweralkyl ether alcohols in an amount of 1 to 5 parts, and the rest is water in an amount to complete said composition. While the references does not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60 is the property of the composition, since Kurginski discloses the same sodium salt of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Kurginski discloses the same sodium salt of EDTA as that recited in the instant invention, the composition should possess claimed properties.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceedings Appendix

The Board is directed to an Appeal and associated Appeal Brief for U.S. Patent Application Serial No. 10/313,844.

Respectfully submitted,

Shobha Kantamneni
October 23 2006

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